REMARKS

Claims 95-100, 105-108, 110, 113, 115, 126 and 127 are pending. Claims 95-100, 113, 115, 126 and 127 are rejected. Claims 1-112 and 114-149 have been canceled. Claims 150-156 have been added. Further examination and consideration is requested in light of the claim amendments and the remarks that follow.

New Matter

The abstract has been objected to as introducing new matter, and an amended abstract has been presented. The amended abstract re-introduces the language from the original abstract regarding the joining of the CDRs to the FRs. The reference to fragments in the abstract has not been removed, as such language is supported by the original specification at paragraphs 0046 and 0048, *inter alia*.

Non-statutory Double Patenting Rejection

The claims were rejected on the ground of non-statutory obviousness-type double patenting over claims 25-27 of U.S. Patent No. 6,187,287. Forwarded herewith is a terminal disclaimer to obviate this rejection.

Rejection of Claims Under 35 USC 112, 1st Paragraph

Claims 95-100 were rejected under 35 USC 112, 1st paragraph for failure to comply with the written description requirement as reciting single CDRs. While isolated polynucleotides encoding single CDRs are described in the specification, in order to advance prosecution claims 95-100 have been canceled.

Claim 115 was rejected under 35 USC 112, 1st paragraph for failure to comply with the written description requirement as reciting fragments. Antigen-binding fragments are clearly described in the specification at paragraphs 0046, 0048, 0056 and Examples 4, 6 and 9.

Claims 113, 126 and 127 are rejected under 35 USC 112, 1st paragraph for failure to comply with the written description requirement as

> encompassing nucleic acids encoding chimeric antibodies containing FR regions not derived from LL2 and there is no disclosure of such nucleic acids in the specification as originally filed. For example, there is no disclosure in the specification of chimeric antibodies with FRs derived from other murine species.

Claim 113 has been amended to recite "framework regions (FRs) of light and heavy chain variable regions of *one or more human antibodies*." This recitation is clearly supported by the specification ("humanization of the chimeric monoclonal antibody by replacing the murine FR sequences in cLL2 with that of human framework regions" – paragraph 0036). This amendment clearly obviates the stated basis for rejection.

Claims 126, 136 and 146 are rejected under 35 USC 112, 1st paragraph, for failure to comply with the written description requirement for disclosing "expression vectors" rather than "mammalian expression vectors." It is noted that claims 136 and 146 were not pending at the time of this Action. Claim 126 has been replaced by new claim 155 which recites a mammalian expression vector.

Claims 95-100, 113, 126 and 127 are rejected under Section 102(b) based on Leung *et al.* (US5789554). Leung is the parent of the present application, but is cited under Section 102(b) because the examiner urges that "the scope of the claims under consideration also encompasses additional embodiments which constitute new matter as per above." However, the examiner has only objected to the amended abstract as constituting "new matter" and has not objected to the claims as encompassing new matter. The only non art-based rejection with respect to the claims above is a rejection for lack of written description.

It is submitted that the specification provides a clear written description of the claims as amended. The claims now recite all of the CDRs. In addition, independent claim 113 has been amended to recite framework regions (FRs) of light and heavy chain variable regions of one or more human antibodies. The priority document for this application clearly describes isolated polynucleotides that include murine CDRs and FRs of "one or more human antibodies" as recited. For example, Example 1 discloses an antibody in which "REI and EU FRs were selected as the human frameworks onto which the CDRs for LL2 VK and VH were grafted, respectively…[and] the FR4 sequence of NEWM, however, rather than

that of EU, was used to replace the EU FR4 sequence for the humanization of LL2 heavy chain." Thus, each and every element of the presently claimed invention is described in the priority document, and US5789554 is not a proper reference against the present claims.

Claims including the recitation regarding the FRs are properly considered in the current examination, as they recite the elected sequences and are readable on the elected species. Moreover, and do not recite non-elected sequences. New claim 153 which more particularly recites the sequences of the FRs also is properly considered in the current examination, as it is readable on the elected species which specifies the CDRs.

Rejection of Claims Under 35 USC 103

The claims are rejected under 35 USC 103(a) as obvious over Goldenberg *et al.*, in view of Morrison *et al.*, Cabilly *et al.*, Boss *et al.*, Orlandi *et al.* and Huston *et al.* (US Patent 5,258,498). The examiner asserts that "Goldenberg *et al.* teach the murine LL2 monoclonal antibody and hybridoma producing said antibody." The examiner further asserts that it would have been obvious to apply the methods of Morrison, concerning chimeric antibody production, to the monoclonal antibody LL2 disclosed in Goldenberg to produce chimeric or humanized LL2 antibodies or fragments.

Applicants respectfully traverse. There is no disclosure in Goldenberg *et al.* of the CDR sequences used to construct the claimed chimeric or humanized LL2 antibodies. Nor was the LL2 antibody publicly available as of the instant application's filing date. Thus, without either the CDR sequences used or a source of the mouse LL2 mAb, the skilled artisan would have had no way to construct the claimed humanized or chimeric LL2 antibodies or fragments thereof, which depend on the incorporation of LL2 CDR sequence. In response, the examiner urges that "there is no evidence of record regarding the lack of public availability of the LL2 antibody or hybridoma producing said antibody." However, it is the examiner's burden in the first instance to provide evidence that the CDR sequences used or a source of the murine LL2 mAb were available prior to applicant's priority date. Failing to do so, the examiner impermissibly attempts to shift a burden to applicants to prove a negative, *i.e.*, that the sequences or antibody were not publicly available. The

examiner has failed to set forth a *prima facie* case of obviousness, therefore withdrawal of the rejection is respectfully requested.

If there are any problems with this response, or if the examiner believes that a telephone interview would advance the prosecution of the present application, Applicant's attorney would appreciate a telephone call.

Respectfully submitted,

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